REMARKS

Claims 1-17 are pending in the instant application. Claims 6, 9-14 and 16 have been withdrawn from consideration by the Examiner and subsequently canceled without prejudice by Applicants herein. Claims 1-5, 7, 8, 15 and 17 have been rejected. Claim 1 and 15 have been amended. Claim 17 has been canceled. New claims 18 through 23 have been added. Support for the amendments is provided in the specification at page 14 through page 16, page 32 through page 33, and Example 1. Thus, no new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Finality of Restriction Requirement

The Examiner has made final the Restriction Requirement as set forth in the Communication mailed October 15, 2003. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have canceled claims 6, 9-14 and 16 without prejudice. Further, Applicants have amended the claims to be drawn to the elected sequences. However, in light of the finality of this Restriction Requirement, Applicants reserve the right to file a divisional application to the canceled subject matter.

II. Rejection of Claims 1-5, 7, 8, 15 and 17 have been rejected under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph

Claims 1-5, 7, 8, 15 and 17 have been rejected under 35 U.S.C. § 101 as the Examiner suggests that the claimed invention lacks patentable utility. Further, these claims have been rejected under 35 U.S.C. § 112, first paragraph, as the Examiner suggests that it would require undue experimentation for one of skill in the art to use the claimed nucleic acids for prostate malignancy detection.

Further, with respect to claim 17, the Examiner suggests that there is no support in the specification and prior art for the asserted use of the nucleic acid with SEQ ID NO:19 or 20 as a vaccine.

Applicants respectfully traverse this rejection.

The instant application claims the benefit of priority from U.S. Provisional Application Serial No. 60/249,992, filed November 20, 2000, the entire contents of which were incorporated by reference in their entirety into the instant application. See page 1, lines 4-6 of the instant application. In the priority application, parent sequence SEQ ID NO:19, referred to therein as SEQ ID NO:16 (see Sequence Listing of instant application), was demonstrated by suppression subtractive hybridization to be a

breast cancer specific marker. These experiments described at pages 25 through 27 of the provisional application, which demonstrate utility of the instant claimed invention, have been incorporated into the instant application as Example 1a at page 118, line 40. No new matter is added by this amendment.

The case law on utility is quite clear; mere identification of a pharmacological activity of a claimed compound that is relevant to an asserted pharmacological use provides an immediate benefit to the public and thus satisfies the utility requirement. Nelson v. Bowler, 626 F.2d 853, 206 USPQ 881, 883 (CCPA 1980). Clearly identification of SEQ ID NO:16, a related sequence to SEQ ID NO:19 and 20 as being a breast cancer specific marker constitutes a pharmacological activity relevant to the asserted use as a diagnostic for breast cancer, thus satisfying the utility requirement.

Applicants have canceled claim 17 thus mooting rejections relating to this claim.

Withdrawal of these rejections under 35 U.S.C. § 101 and §112, first paragraph, is respectfully requested in light of the claim amendments and the above remarks.

IV. Rejection of Claim 1-5, 7 and 8 under 35 U.S.C. § 112, first paragraph - Written Description

Claims 1-5, 7 and 8 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner suggests that the specification fails to provide descriptive support for the generic claim to "a nucleic acid that selectively hybridizes to the nucleic acid comprising SEQ ID NO:19 or 20". The Examiner also suggests that the large genus of nucleic acids having at least 60% sequence identity to SEQ ID NO:19 or 20 is not supported by the written description of the instant application.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 1, part (c), to state that the nucleic acid sequence hybridizes under stringent conditions and have defined these conditions in accordance with teachings at page 14 through 16 of the instant specification. Applicants have amended part (d) of claim 1 to state that the nucleic acid sequence has 85% identity over a length of 400 nucleotides in accordance with teachings at page 32 through 33.

Detailed methodologies for ascertaining sequences which meet the structural limitations of the instant amended claims are set

forth in the specification at page 13 through 16 and 32 through 33. Further methods for assessing percent sequence identity and/or the ability of a nucleic acid sequence to hybridize under stringent conditions to a disclosed reference sequence are performed routinely by those skilled in the art. Thus, upon discovery of the instant claimed nucleic acid sequence of SEQ ID NO:19 or 20 and their specificity in breast tumor tissues, Applicants were clearly in possession of additional nucleic acid sequences identified in accordance with routine procedures based upon this reference sequence. Further, the instant specification and its teachings clearly place the public in possession of these sequences as well.

Thus, the instant specification and the claims as amended meet the "essential goal" of the written description requirements of 35 U.S.C. § 112, first paragraph as set forth in MPEP § 2163.

Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, is therefore respectfully requested.

V. Rejection of Claims 1, 2, 4, 5, 7 and 8 under 35 U.S.C. § 102(e)

Claims 1, 2, 4, 5, 7 and 8 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Salceda et al. (US2002/0037250). The Examiner suggests that Salceda teach sequences with SEQ ID

NO:17 which is 83.6% identical to SEQ ID NO:19, with bp 1-391 being 93.9% identical to bp 1-408 of SEQ ID NO:19. Thus, the Examiner suggests that SEQ ID NO:17 has at least 60% sequence identity to SEQ ID NO:19 and will hybridize specifically to SEQ ID NO:19. Further, the Examiner suggests that SEQ ID NO:17 is 29.4% identical to SEQ ID NO:20, with bp 1-391 being 93.6% identical to bp 747-1154 of SEQ ID NO:20. The Examiner also suggests that SEQ ID NO:17 is a human cDNA and vectors and host cells are taught.

Applicants respectfully traverse this rejection.

It is respectfully pointed out that the claims of the instant application have been amended. Claim 1 is now drawn to an isolated nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 19 or 20, a nucleic acid molecule that hybridizes under stringent hybridization conditions of 50% formamide/6X SSC at 42°C for at least 10 hours or 6X SSC at 68°C without formamide for at least 10 hours to the nucleic acid molecule comprising SEQ ID NO:19 or 20, or a nucleic acid molecule having at least 85% sequence identity over a length of 400 nucleotides to the nucleic acid molecule of (a).

SEQ ID NO:17 of Salceda et al. does not meet the limitations of the claims as amended as it does not share 85% sequence identity over a length of 400 nucleotides to SEQ ID NO:19 or 20 and would

not hybridize under the defined stringent conditions given the region of dissimilarity in the middle of SEQ ID NO:17 and SEQ ID NO:19. Thus, in accordance with MPEP § 2131, this reference cannot anticipate the amended claims.

Withdrawal of this rejection is therefore respectfully requested.

VI. Rejection of Claim 15 under 35 U.S.C. § 102(b)

Claim 15 has been rejected under 35 U.S.C. § 102(b) as being anticipated by GibcoBRL Catalog (p. 7-7, 1993-94). The Examiner suggests that this catalog teaches a kit with random primers which are suitable for DNA synthesis. Thus, the Examiner suggests that since any DNA can be amplified with such primers, they can be used to detect the nucleic acid comprising SEQ ID NO:19 and 20.

Applicants respectfully traverse this rejection.

MPEP §2131 is quite clear; to anticipate a claim the reference must teach all the elements of the claimed invention. Claim 15 is drawn to a kit for detecting a risk of cancer or presence of cancer in a patient. The kit comprises a means for determining the presence of a nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 19 or 20, a nucleic acid molecule that hybridizes under stringent hybridization conditions of 50%

formamide/6X SSC at 42°C for at least 10 hours or 6X SSC at 68°C without formamide for at least 10 hours to the nucleic acid molecule comprising SEQ ID NO:19 or 20, or a nucleic acid molecule having at least 85% sequence identity over a length of 400 nucleotides to the nucleic acid molecule comprising SEQ ID NO:19 or 20. The vague teachings of the Gibco Catalog regarding a kit for random primer generation in no way teaches a means for detection of these specific nucleic acid molecules.

Thus, withdrawal of this rejection under 35 U.S.C. § 102(b) is respectfully requested.

VII. Provisional Obviousness-type Double Patenting Rejection

Claims 1, 7 and 8 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3 and 4 of copending application No. 09/817,318.

Applicants respectfully traverse this rejection.

Claims of copending application No. 09/817,318 are drawn to an isolated nucleic acid molecule comprising SEQ ID NO:1 while claims of the instant application are limited herein to an isolated nucleic acid molecule comprising SEQ ID NO:19 or 20, nucleic acid molecules that hybridize under stringent hybridization conditions

of 50% formamide/6X SSC at 42°C for at least 10 hours or 6X SSC at 68°C without formamide for at least 10 hours to the nucleic acid molecule of SEQ ID NO:19 or 20, or nucleic acid molecules having at least 85% sequence identity over a length of 400 nucleotides to the nucleic acid molecule of SEQ ID NO:19 or 20. SEQ ID NO:1 is different from SEQ ID NO:19 and 20. Thus, the diagnostic cancer markers of the instant application as now claimed are not obvious over the allowed claims of copending application No. 09/817,318.

Thus, withdrawal of this rejection under the doctrine of obviousness type patenting is respectfully requested.

VIII. Supplemental IDS

Applicants are submitting herewith a Supplemental IDS for review and consideration by the Examiner. Acknowledgment of receipt and review of references cited therein by the Examiner is respectfully requested.

IX. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly,

favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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